(3) Voting and nonvoting advisory committee members who are members of the uniformed services, including the Commissioned Corps of the Public Health Service, provide service on Food and Drug Administration advisory committees as part of their assigned functions, are not appointed as special government employees, but are reimbursed by the Food and Drug Administration for travel expenses.

(b) Notwithstanding the member's primary residence, an advisory committee member, while attending meetings of the full committee or a subcommittee, will be paid whether the meetings are held in the Washington, DC, area or elsewhere.

(c) A committee member who participates in any agency-directed assignment will be paid at an hourly rate when doing assigned work at home, a place of business, or in an FDA facility located within the member's commuting area, and at a daily rate when required to travel outside of that commuting area to perform the assignment. A committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment that meets the following criteria:

(i) An activity that requires undertaking a definitive study. The activity must produce a tangible end product, usually a written report. Examples are:

(*a*) An analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA;

(*b*) The performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation;

(*c*) The preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and

(*d*) The design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) A committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of the committee member's own assignment, can be compensated. Should this preparatory work by members collectively result in an end product of the committee, this is to be considered normal meeting preparation and committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when a committee member's ordinary pursuits are interrupted for the substantial portion of an additional day beyond the day or days spent in performing those services, and as a consequence the committee member loses some regular compensation. This applies on weekends and holidays if the special Government employee loses income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988]

Subpart F—Standing Advisory Committees

§ 14.100 List of standing advisory committees.

Standing advisory committees and the dates of their establishment are as follows:

(a) *Office of the Commissioner—*

(1) *Board of Tea Experts.*

(i) Date established: March 2, 1897.

(ii) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States under 21 U.S.C. 42.

(2) *Science Board to the Food and Drug Administration.*

(i) Date established: June 26, 1992.

(ii) Function: The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency

on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

(3) *Pediatric Advisory Committee.*

(i) Date established: June 18, 2004.

(ii) Function: Advises on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which the Food and Drug Administration has regulatory responsibility.

(4) *Risk Communication Advisory Committee.*

(i) Date rechartered: July 9, 2009.

(ii) Function: The committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. The committee also reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.

(5) *Tobacco Products Scientific Advisory Committee.*

(i) Date Established: August 12, 2009.

(ii) Function: The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner of Food and Drugs. Specifically, the committee will submit reports and recommendations on tobacco-related topics, including: The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities; the nature and impact of the use of dissolvable tobacco products on the public health, including such use on children; the effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and any application submitted by a manufacturer for a modified risk tobacco product. The committee may provide recommendations to the Secretary of Health and Human Services regarding any regulations to be issued under the Federal Food, Drug, and Cosmetic Act and may review any applications for new tobacco products or petitions for exemption under section 906(e) of the Family Smoking Prevention and Tobacco Control Act. The committee may consider and provide recommendations on any other matter as provided in the Family Smoking Prevention and Tobacco Control Act.

(b) *Center for Biologics Evaluation and Research—*

(1) *Allergenic Products Advisory Committee.*

(i) Date established: July 9, 1984.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

(2) *Cellular, Tissue and Gene Therapies Advisory Committee.*

(i) Date established: October 28, 1988.

(ii) Function: Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

(3) *Blood Products Advisory Committee.*

(i) Date established: May 13, 1980.

(ii) Function: Reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

(4) [Reserved]

(5) *Vaccines and Related Biological Products Advisory Committee*—(i) Date established: December 31, 1979.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

(6) *Transmissible Spongiform Encephalopathies Advisory Committee*—(i) Date established: June 21, 1995.

(ii) Function: Reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spngiform encephalopathies having an impact on the public health.

(c) *Center for Drug Evaluation and Research*—

(1) *Anesthetic and Life Support Drugs Advisory Committee.*

(i) Date established: May 1, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the field of anesthesiology and surgery.

(2) *Anti-Infective Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

(3) *Antiviral Drugs Advisory Committee.*

(i) *Date established:* February 15, 1989.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

(4) *Arthritis Advisory Committee.*

(i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

(5) *Cardiovascular and Renal Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

(6) *Dermatologic and Ophthalmic Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

(7) *Drug Safety and Risk Management Advisory Committee.*

(i) Date established: May 31, 1978.

(ii) Function: Reviews and evaluates data on risk management plans, provides active surveillance methodologies, trademark studies, methodologies for risk management communication, and related issues.

(8) *Endocrinologic and Metabolic Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

(9) *Advisory Committee for Reproductive Health Drugs.*

(i) Date established: March 23, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

(10) *Gastrointestinal Drugs Advisory Committee.*

(i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases.

(11) *Oncologic Drugs Advisory Committee.*

(i) Date established: September 1, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

(12) *Peripheral and Central Nervous System Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of

marketed and investigational human drugs for use in neurological disease.

(13) *Psychopharmacologic Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

(14) *Pulmonary-Allergy Drugs Advisory Committee.*

(i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(15) *Medical Imaging Drugs Advisory Committee.*

(i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

(16) *Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.*

(i) Date established: January 22, 1990.

(ii) Function: The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

(17) *Nonprescription Drugs Advisory Committee.*

(i) Date established: August 27, 1991.

(ii) Functions: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

(18) *Pharmacy Compounding Advisory Committee.*

(i) Date established: February 12, 1998.

(ii) Function: Provides advice on scientific, technical, and medical issues concerning drug compounding by pharmacists and licensed practitioners.

(d) *Center for Devices and Radiological Health—*

(1) *Medical Devices Advisory Committee.*

(i) *Date established:* October 27, 1990.

(ii) *Function:* Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

(2) *Device Good Manufacturing Practice Advisory Committee.*

(i) Date established: May 17, 1987.

(ii) Function: Reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

(3) *Technical Electronic Product Radiation Safety Standards Committee.*

(i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(4) *National Mammography Quality Assurance Advisory Committee.*

(i) Date established: July 6, 1993.

(ii) Function: Advises on developing appropriate quality standards and regulations for the use of mammography facilities.

(e) *National Center for Toxicological Research—Science Advisory Board.*

(1) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research

program that will assist the Commissioner of Food and Drugs tofulfill regulatory responsibilities.

(f) *Center for Veterinary Medicine.*

Veterinary Medicine Advisory Committee.

(1) Date established: April 24, 1984.

(2) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

(g) *Center for Food Safety and Applied Nutrition—Food Advisory Committee.*

(1) Date established: December 15, 1991.

(2) Function: The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

[54 FR 9036, Mar. 3, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §14.100, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established in accordance with the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC—

(1) May propose electronic product radiation safety standards to the Commissioner for consideration;

(2) Provides consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f; and

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action on performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or an amendment of an existing standard, before issuing a proposed regulation in the FEDERAL REGISTER the Commissioner will submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting will be sent to members whenever possible at least 2 weeks before the meeting.

(c) Ten members constitute a quorum, provided at least three members are present from each group specified in 42 U.S.C. 263f(f)(1)(A) and in §14.127(a), i.e., Government, industry, and the public.

(d) The chairman of TEPRSSC will ordinarily submit a report to the Commissioner of the committee's consideration of any proposed performance standard for an electronic product within 60 days after consideration. If the chairman believes that more time is needed, the chairman will inform the Director of the Center for Devices and Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) Sections 14.1 through 14.7 apply to TEPRSSC, except where other provisions are specifically included in §§14.120 through 14.130.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 14.127 Membership of TEPRSSC.

(a) The Commissioner will appoint the members after consultation with public and private organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC consists of 15 members, each of whom is technically qualified by training and experienced in one or